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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,337	12/07/2001	Patrick Benoit	08888.0530	9440

7590 01/26/2005

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/005,337	BENOIT ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *28 December 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *4,5,7,21,23,25,27,31,33 and 39*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): Applicants reply has overcome the 35 U.S.C. 112, first paragraph rejection against claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39 as failing to comply with the enablement requirement. Specifically, the Examiner has withdrawn this rejection in view of Applicants arguments that Example 10 and Figure 8 demonstrates transgene expression following intracardiac administration of a plasmid vector which is devoid of AAV-ITR sequences.

Continuation of 5. does NOT place the application in condition for allowance because: The request for reconsideration has been considered, but does not place the application in condition for allowance because claims 4, 5, 7, 21, 23, 25, 27, 31, 33 and 39 would remain rejected under 35 U.S.C. 102(b) as being anticipated by Kuo et al. (Development, 1999 Vol. 126:4223-4234). In response to this rejection, Applicants argue that in Regents of the University of California v. Eli Lilly and Co., the Federal Circuit held that the sequence of rat insulin does not provide an adequate written description of the cDNA encoding human insulin. Applicants further argue that the claims recite sequences upstream of the gene encoding human CARP, where Kuo et al. disclose only the mouse CARP gene and the activity of 5' cis regulatory elements. Applicants contend that based on the Lilly decision, Kuo et al. fail to provide adequate written description and do not anticipate claims to the human CARP gene. These arguments have been fully considered, but are not found persuasive. First, Applicants argue the Lilly decision in which the Federal Circuit held that the sequence of rat insulin does not provide an adequate written description of the cDNA encoding human insulin. It is noted that the Lilly decision concerns those rejections made under 35 U.S.C. 112, first paragraph for written description, and not 35 U.S.C. 102 rejections for anticipation. It is unclear how the Lilly decision is relevant to the instant art rejection, since the Lilly decision is primarily based on written description. Second, the claims recite a polynucleotide comprising a fragment of SEQ ID NO:2, wherein said polynucleotide, in the absence of ITR sequences, induces expression in cardiac cells in vivo. Applicants have not disclosed what the term "fragment" is intended to encompass, therefore the Examiner has given the term "fragment" its broadest reasonable interpretation. Kuo et al. disclose deletions from the 5'-end of a 2.5 kb fragment upstream of the coding sequence of mouse CARP were made and showed that a region of 213 bp of the promoter between nucleotides -166 and +47, relative to the transcription start position +1, was sufficient to confer cardiospecific expression in vitro. Kuo et al. also report the ability of such sequences to regulate region-specific transgene expression in cardiac and skeletal muscle cells at an early stage of embryonic development. In the Examiner's eyes, the 213 bp fragment of the mouse CARP promoter, between nucleotides -166 and +47, which confers cardiac specific expression, disclosed by Kuo et al. consists of a fragment of SEQ ID NO:2. Therefore, the disclosure of Kuo et al. meets all the structural limitations of the claims, and therefore is considered to possess the functional limitations of the claim, namely to ability to induce cardiac-specific expression in vivo, absent evidence to the contrary. Therefore, the disclosure of Kuo et al. anticipates claims 4, 5, 7, 21, 23, 25, 27, 31, 33, and 39.